

**REMARKS**

Claims 58-64 are pending in this application. Support for the new claims can be found in the claims as originally filed and on page 16, lines 11-13, of the specification. These new claims do not add new matter. Applicants respectfully request reconsideration of these claims in light of the amendments and remarks made herein.

**Sequence Requirements**

On page 2 of the Office Action, the Office asserted that the application contains sequence disclosures in Figures 1A-1E , but that no sequence identifiers are provided. Applicants have amended the description of Figure 1 in the Brief Description of the Drawings, which begins on page 9, line 12, and continues to page 10, line 16, by including the appropriate sequence identifiers.

In addition, the Office included a Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. In this Notice, the Office asserted that the application does not comply with the requirements of 37 C.F.R. § 1.821-1.825 because the application contains neither a paper copy of a Sequence Listing nor a computer readable form of a Sequence Listing. Applicants note that a Sequence Listing, on paper, was filed on December 15, 2003, in response to the Notice to File Missing Parts. A Request for Transfer of Form Under 37 C.F.R. § 1.821(e), referring to the computer readable form of the Sequence Listing in parent application Serial No. 09/549,519 was also filed at that time. Copies of these documents, as well as the stamped postcard indicating receipt in the U.S. Patent and Trademark Office, are attached as Exhibit A. Applicants submit that these documents fulfill the requirements under the Sequence Rules and, thus,

respectfully request that any objection or rejection made because of failure to comply with those Rules be withdrawn.

Information Disclosure Statement

In items 4 and 5 of the Office Action, the Office asserted that a legible copy of the editorial from the journal Vaccine was not submitted in the IDS filed May 11, 2004. Applicants have attached a copy of this editorial and respectfully request that it be considered.

Priority

In items 6 and 7 of the Office Action, the Office indicated that the specification does not contain a reference to the prior applications on which the priority is based. In fact, Applicants amended the specification to include a statement of priority in the Transmittal Letter included with the filing of this application. Specifically, the specification was amended to insert the following new paragraph before the first line: "This is a continuation of Application No. 09/549,519, filed April 14, 2000, and claims the benefit of U.S. provisional application no. 60/129,501, filed April 15, 1999, all of which are incorporated herein by reference." Applicants have attached a copy of this Transmittal Letter and the stamped postcard, indicating receipt by the U.S. Patent and Trademark Office, as Exhibit B. In addition, Applicants note that this chain of priority was correctly indicated on the Filing Receipt issued by the Office.

35 U.S.C. § 112, second paragraph

In items 8 and 9 of the Office Action, the Office rejected claims 43-46 under 35 U.S.C. § 112, second paragraph, because it asserted that claim 43 is indefinite. Specifically, the Office asserted that it is not clear whether claim 43 refers to a

polypeptide encoded by the nucleotide sequence of a partial glycoprotein or the nucleotide sequence of an entire plasmid or vector.

Applicants note that claims 43-46 have been cancelled. New claims 58-64 recite a polynucleotide that encodes the recited polypeptide. Thus, these claims are not indefinite and Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 112, first paragraph

In items 12 through 16 of the Office Action, the Office asserted that claims 44-46 fail to comply with the enablement requirement under 35 U.S.C. §112, first paragraph. Specifically, the Office asserted that the specification does not provide a teaching of the structure of the polypeptide encoded by an entire plasmid or viral vector polypeptide.

Applicants note that claims 44-46 have been canceled. New claims 58-64 recite a polynucleotide that encodes the recited polypeptide. Thus, the claims are enabled.

In items 17 through 24, the Office also rejected claims 46 and 50 under 35 U.S.C. § 112, first paragraph, because it asserted that the specification does not provide an enabling description of an immunogenic composition comprising a polypeptide encoded by the entire polynucleotide of a plasmid or viral vector.

Claims 46 and 50 have been canceled in this Amendment and new claims 58-64 recite a polynucleotide that encodes the recited polypeptide. Thus, the claims are enabled.

Because the specification does not fail to enable the claimed invention, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

35 U.S.C. § 102

In items 26 and 27 of the Office Action, the Office rejected claims 43 and 47 under 35 U.S.C. § 102(a) as being anticipated by Jallet et al., J. Virol. (1999) vol. 73, pp. 225-233 ("Jallet"). The Office asserted that Jallet discloses a polynucleotide in a carrier plasmid, wherein the polynucleotide encodes a part of the lyssavirus glycoprotein including site III, rather than the entire sequence of the glycoprotein.

Applicants traverse this rejection because Jallet discloses their own work and therefore is not prior art because "one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner and form which otherwise would fall under the § 102(a)." *In re Katz*, 215 U.S.P.Q. 14, 17 (C.C.P.A. 1982). Furthermore, like the situation adjudicated in *Katz*, there are several authors of Jallet who are not inventors of the claimed invention. These authors did not make a contribution to the claimed invention. Instead, they either merely performed studies or constructed plasmids under the direction of at least one of the named inventors, as described in the attached Declaration Under 37 C.F.R. § 1.132, executed by applicant Noël Tordo. These contributions do not amount to inventorship. Thus, Jallet cannot be asserted as prior art against the claimed invention.

In addition, in items 29 through 34, the Office rejected the claims as being anticipated under 35 U.S.C. § 102(b) by either Mebatsion, et al., (1995) J. Virol., vol. 69, pp. 1444-51 ("Mebatsion"), Wunner, et al., (1985) Ann. Inst. Pasteur/Virol., vol. 136, pp. 353-62 ("Wunner"), and Tordo, et al., (1993) Virol., vol. 194, pp. 59-69 ("Tordo"). The

Office asserted that each of Mebatsion, Wunner, and Tordo disclose the site III of a lyssavirus glycoprotein.

Neither Mebatsion, Wunner, nor Tordo discloses a polynucleotide that is a combination of a site III polypeptide from genotype GT1 strain lyssavirus and a site II polypeptide from genotype GT5 strain, as recited in new claims 58-64. Without disclosure of these elements, neither Mebatsion, Wunner, nor Tordo can anticipate the claimed invention. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 102 be withdrawn.

35 U.S.C. § 103

In items 36 through 41 the Office rejected claims 47-49 and 53 under 35 U.S.C. §103 as being unpatentable over Bahloul, et al., Vaccine, vol. 16, pp. 417-25 (1998) ("Bahloul") and Wojczyk, et al., Protein Expression and Purification, vol. 7, pp. 183-93 (1996) ("Wojczyk"). The Office asserted that Bahloul discloses a polypeptide expressed in a carrier protein wherein the polypeptide encodes a part of the glycoprotein that includes the lyssavirus site III. The Office also asserted that Wojczyk teaches methods to isolate recombinant viral glycoproteins and, in addition, that Wunner teaches immunogenic compositions comprising antigens that cover site III amino acid residues from the rabies virus glycoprotein.

Applicants note that claims 47-49 and 53 have been canceled. Furthermore, Applicants respond that Bahloul does not disclose a polynucleotide encoding a site III polypeptide sequence of a lyssavirus glycoprotein from a genotype GT1 and also a polynucleotide encoding a site II polypeptide sequence of lyssavirus glycoprotein from genotype GT5 strain, as claimed in new claim 58 and the claims that depend from it.

Without disclosure of both of these sites in a polynucleotide, the claimed invention is not obvious.

The Office also rejected claims 47-49 and 53 under 35 U.S.C. § 103 as being unpatentable over Jallet, Wunner, and Wojczyk. As indicated above, Jallet is not available as prior art because it is Applicants' own work and was available less than one year after the priority date of the instant application. Furthermore, because none of the references cited by the Office in this rejection under 35 U.S.C. § 103 discloses a polynucleotide encoding a site III polypeptide sequence of a lyssavirus glycoprotein from a genotype GT1 strain and also a polynucleotide encoding a site II polypeptide sequence of a lyssavirus glycoprotein from a genotype GT5 strain, as claimed in new claims 58 and its dependent claims 59-64, the Office has not demonstrated that the claimed invention is obvious.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §103 be withdrawn.

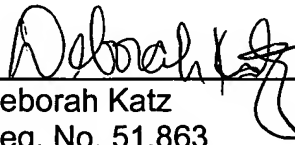
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: July 28, 2006

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**Attachments:**

- 1) Editorial from *Vaccine*, vol. 14, no. 7, pp. 579-732 (1996) at pp. 579-81;
- 2) Exhibit A: Sequence Listing, Request for Transfer of Form and stamped postcard;
- 3) Exhibit B: Transmittal Letter and stamped postcard,
- 4) Exhibit C: Declaration Pursuant to 37 C.F.R. § 1.132.



### Editorial

In recent years, we have witnessed an increasing international interest in vaccines, stimulated not only by spectacular advances in immunology and molecular biology, but also by increasing political awareness of vaccination as an extremely potent tool in public health. Furthermore, technological developments may significantly reduce the cost of vaccine development and production, and better utilisation of common resources is likely to reduce the high costs of clinical trials. Ultimately, safe and efficient vaccines should be affordable wherever they are needed.

In Europe, a number of recent activities reflect this renewed interest in vaccinology. Thus, new legislation adopted by the European Union prompted the creation of the London based European Medicines Evaluation Agency (EMA), which in collaboration with the European Pharmacopoeia in Strasbourg facilitates the introduction of new vaccines to the European market. And on the industrial side, a working group representing most of the European Vaccine Manufacturers (EVM) has been established within the European Pharmaceutical Manufacturers Association.

Within the Community's Research and Development Framework Programme, the importance of vaccine research is increasingly recognised. Both the Biomed2 and the Biotechnical programmes are strongly promoting transnational European networks in this field. Another DG XII programme, INCO-DC (Scientific and Technological Cooperation with Developing Countries), encourages collaboration in vaccine research between scientists in Europe and developing countries, with emphasis on the control of infectious diseases in the South.

At the beginning of 1995, Commissioners Mrs. Cresson and Mr. Bangemann created a series of industry-research interactive Task Forces, one of which concerns Vaccines and Viral Diseases. This Task Force has already organised a number of consultations with leading scientists and industrial experts in order to establish the priorities for its research and development agenda.

Before this crucial development, DG XII with the combined resources of the two programmes COST (Co-operation, Science and Technology in Europe) and STD (Life Sciences and Technologies for Developing Countries) launched a large scale co-ordination exercise, known as the COST/STD Initiative, under the scientific leadership of Professor Bjarne Bjorvatn, Centre for International Health, University of Bergen, Norway.

At a policy meeting in Bergen in October 1994, 30 representatives of European industry and academia identified a number of problem areas as well as important challenges to optimal European collaboration in vaccinology. Nine of these areas have been selected for more extensive scrutiny by expert panels. In addition to the establishment of a data bank covering 350 European research projects in human vaccinology the most important outcome of the COST/STD Initiative is undoubtedly contained in the conclusions and recommendations of these expert panel reports, which were finalised during the last few months. These reports are now published in this special issue of "Vaccine".

## Foreword

Realising that improved collaboration in vaccinology will serve European as well as global health, and in addition improve the competitive strength of the relevant European science and industry, the DG XII programmes COST and STD-3 in 1994 agreed jointly to launch a 2 year project to strengthen European efforts in the field of human vaccine research and development. A major outcome of this initiative is the present collection of reports from several expert panels, each dealing with a particular problem area or an important challenge to European vaccinology. Following a policy meeting in Bergen in 1994, where central issues in need of further exploration were identified, the resulting draft reports were discussed by a large and representative group of experts in Bergen in November 1995. In this separate issue of Vaccine these reports are presented in their revised and final form.

Each of the expert panels were asked to critically review their respective field and then to provide recommendations with regard both to direction of future research and the removal of bottlenecks preventing optimal utilisation of European resources.

These recommendations should be of considerable interest not only to scientists and the vaccine manufacturers, but also to politicians and administrators involved in the field of vaccinology. It is very encouraging that some of the conclusions obtained through this initiative already are adopted in EC policy documents. In a similar fashion, national authorities responsible for public health spending may find useful information for their respective programmes.

Whereas the tremendous potential of vaccines as a cost-efficient prophylactic tool has been amply demonstrated for a large number of infectious diseases, in future, several non-infectious disorders may be added to the list of vaccine preventable diseases. Ultimately, a more rational balance must therefore be achieved between cost-efficient prophylactic spending, and the often very costly therapeutic measures, that now dominate our health budgets.

As the co-ordinator of the COST/STD Initiative I am very pleased to see the work of the expert panels successfully completed. I would like to thank the chairpersons and other panel members for excellent performance in spite of their already overloaded schedules and the tough deadlines set for this task. The names of the expert panel members are found on the front page of the respective reports. Furthermore, I would like to thank Mr. Rainer Gerold and Mr. Bruno Hansen, Directors of the European Commission programmes for Life Sciences Research and International Co-operation, respectively, who were kind enough to write the Editorial, as well as the many Scientific Officers within the Commission who offered their advice and collaboration throughout this project. My thanks also go to the scientists from inside and outside Europe, to the industrial experts within and outside the group of European Vaccine Manufacturers and to the WHO-officials who have served as advisers in connection with this COST/STD Initiative. Some crucial persons are named under the acknowledgement section overleaf.

Bergen and Brussels March 1996

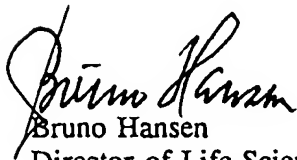
Bjarne BJORVATN

The first report which is entitled "Models for scientific and economic interaction in vaccine research and development", presents some of the current legal and economic constraints of vaccine manufacturing in Europe, and model contracts as guidelines for scientific and economic interaction between scientists and the vaccine producing industry. The next report A European surveillance system for infectious diseases reviews the present surveillance situation in Europe with regard to selected vaccine preventable diseases, and proposes a common European strategy for surveillance. The same authors have written the chapter on Harmonisation of European vaccination programmes which presents current vaccination programmes and discusses essential epidemiological questions concerning individual vaccine preventable disease. Subsequently, the paper A common European network for clinical trials provides advice on how Europe might process most expediently towards a common framework for such trials. In the chapter Concerted efforts in the field of mucosal immunology the authors discuss recent developments in this field, and propose areas where the complementary expertise of European scientists is particularly likely to pay off. The subsequent topic is Vaccine delivery systems where currently available systems are presented and evaluated. In the paper New vaccines, especially new combined vaccines the authors discuss logical combination of such vaccines, and assess possibilities as well as theoretical and practical problems inherent in combined vaccines. Vaccines against tuberculosis reviews current research and proposes strategies for how best to stimulate and organise further collaboration in this field. Finally, the paper entitled Animal models in vaccine research provides practical recommendations and discusses ethical aspects related to animal experiments in vaccine research.

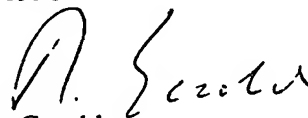
We are confident that this series of reports will be of considerable interests to everybody working in vaccine research and development. In fact, all the above publications contain a lot of updated background information that should be useful even to readers without particular background in vaccinology. We hope, that this exercise will prove to stimulate European research in vaccinology, and contribute to strengthened collaboration on vaccine development between science and industry.

At the level of the European Commission, the recommendations of these expert panels constitute an essential contribution to further development of European policy in this important field.

Brussels, March 1996



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